



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 216

[Docket No. FDA-2015-N-0030]

Extension of the Period before the Food and Drug Administration Intends to Begin Enforcing the Statutory 5 Percent Limit on Out-of-State Distribution of Compounded Human Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; extension of period before enforcement.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the period before FDA intends to begin enforcing the statutory 5 percent limit on distribution of compounded human drug products out of the State in which they are compounded in States that have not entered into a standard memorandum of understanding (MOU) with FDA addressing certain distributions of compounded human drug products. FDA is extending the period, which was scheduled to end on October 27, 2022, until the effective date of a final rule regarding certain distributions of compounded human drug products and publication of an updated standard MOU.

DATES: FDA is extending the period before FDA intends to begin enforcing the statutory 5 percent limit on distribution of compounded human drug products out of the State in which they are compounded in States that have not entered into a standard MOU with FDA as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Dominic Markwordt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5104, Silver Spring, MD 20993-0002, 301-796-9349.

SUPPLEMENTARY INFORMATION: Section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353a) describes the conditions that must be satisfied for drug products compounded by a licensed pharmacist in a State licensed pharmacy or a Federal facility, or a licensed physician, to be exempt from the following sections of the FD&C Act: (1) section 501(a)(2)(B) (21

U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice (CGMP) requirements), (2) section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use), and (3) section 505 (21 U.S.C. 355) (concerning the approval of drugs under new drug applications or abbreviated new drug applications).

One of the conditions to qualify for the exemptions listed in section 503A of the FD&C Act is that: (1) the drug product is compounded in a State that has entered into an MOU with the FDA that addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State or (2) if the drug product is compounded in a State that has not entered into such an MOU, the licensed pharmacist, pharmacy, or physician does not distribute, or cause to be distributed, compounded drug products out of the State in which they are compounded in quantities that exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician (statutory 5 percent limit) (see section 503A(b)(3)(B)(i) and (ii) of the FD&C Act).

In the *Federal Register* of October 27, 2020 (85 FR 68074), FDA announced the availability of a standard MOU describing the responsibilities of a State Board of Pharmacy or other appropriate State agency that chooses to sign the standard MOU in investigating and responding to complaints related to drug products compounded in such State and distributed outside such State and in addressing the interstate distribution of inordinate amounts of compounded human drug products.

In the October 27, 2020, *Federal Register* notice, FDA stated that it was providing a 365-day period that was scheduled to end on October 27, 2021, for States to decide whether to sign the standard MOU before FDA intended to begin enforcing the statutory 5 percent limit in States that do not sign the standard MOU. Soon after announcing the availability of the standard MOU, FDA was sued by several compounding pharmacies regarding the standard MOU in the U.S. District Court for the District of Columbia (*Wellness Pharmacy, Inc. v. Becerra* (D.D.C. Sep. 21, 2021)).

In the *Federal Register* of August 9, 2021 (86 FR 43550), FDA extended the period to October 27, 2022, before FDA intends to begin enforcing the statutory 5 percent limit in States that do not sign the standard MOU.

On September 21, 2021, the Court remanded the standard MOU to FDA to either certify that it will not have a significant economic effect on small businesses or prepare a regulatory flexibility analysis. To undertake this analysis more fully and ensure a robust framework for these important public health protections, FDA intends to engage in notice-and-comment rulemaking regarding certain distributions of compounded human drug products under section 503A of the FD&C Act. FDA considers the standard MOU published in October 2020 to be suspended. This means that during the rulemaking process, FDA will not enter into new agreements with States based on the October 2020 standard MOU. FDA does not expect States that have signed the October 2020 standard MOU to carry out the activities described in the MOU. The October 2020 standard MOU will be updated based on the content of a final rule, and FDA intends to announce a new opportunity for all States to consider and sign the updated standard MOU.

FDA is now extending the period before FDA intends to begin enforcing the statutory 5 percent limit in States that have not entered into a standard MOU with FDA until the effective date of a final rule regarding certain distributions of compounded human drug products under section 503A of the FD&C Act and publication of an updated standard MOU.¹

Dated: October 17, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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¹ The Office of the Federal Register has published this document under the category “Rules and Regulations” pursuant to 1 CFR 5.9(b). We note that the categorization as such for purposes of publication in the Federal Register does not affect the legal content or intent of the document. See, 1 CFR 5.1(c).